Statement of the Patent & Trademark Office Society to the United States Patent & Trademark Office on Interim Guidelines for Examination of Patent Applications Under The 35 U.S.C. 112, First Paragraph "Written Description" Requirement

The Patent & Trademark Office (PTO) has requested comments on the Interim Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement. These "Written Description Guidelines" will be used by PTO personnel in their review of biotechnological patent applications for compliance with the written description requirement in view of *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), and earlier cases *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and *Amgen, Inc. v. Chugai Pharmaceutical C.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

As an organization comprised primarily of patent examiners, the Patent & Trademark Office Society (PTOS) felt comments on these proposed guidelines are of significant concern. In preparing these comments, the PTOS has attempted to ascertain the views of its diverse membership. Although the opinions expressed varied, this statement is what the PTOS believes is representative of its membership. The PTOS appreciates this opportunity to provide comments on this important topic.

The PTOS wishes to comment on the following: 1) scope of the guidelines; (2) the accuracy of the methodology; and 3) the impact these guidelines may have on currently pending applications as well as future applications.

1) Scope of the guidelines

There are three main questions with regards to the scope of these guidelines: (i) are they applicable outside the context of the biotechnological arts; (ii) are they applicable to today's DNA art, as well as, to other areas of biotechnology; and (iii) are they applicable to process and product-by-process claims?

(i) Are the guidelines applicable outside the context of biotechnological inventions?

The PTOS believes that the written description guidelines are only applicable to the unpredictable arts, in particular to certain unpredictable areas of biotechnology, rather than to the predictable arts and that the *Lilly* decision specifically confined its holding to "claims of genetic material" at the time of the *Lilly* patent. The examples in the guidelines are appropriate for this purpose, i.e., product claims to genetic materials. However, a recent court decision in *The Gentry Gallery inc. v. The Berkline Corp.*, 134 F.3d 1473, 1480, 45 USPQ 2d 1498, 1503 (Fed. Cir. 1998) indicates otherwise. This decision invalidated a genus claim in a mechanical patent on a reclining sofa on the ground of a lack of written description. Accordingly, it appears that these guidelines may have broad implications in all technologies, even in arts recognized as being predictable, such as the chemical, mechanical and electrical arts.

Thus, the PTOS believes that the guidelines should be applicable only to the unpredictable arts, in particular to certain areas of biotechnology. However, the scope of the guidelines remains unclear especially in view of this recent decision and in view of the explicit indication that the guidelines apply across the board to all relevant technologies. With that in the mind, the PTOS requests that the PTO revisit the issue as to how these

guidelines apply, if at all, outside the context of the biotechnological arts. In the event the PTO wishes to extend these guidelines to the predictable arts, the PTOS requests that clear guidance in the form of examples and training covering a diverse range of technologies be provided.

ii) Are they applicable to today's DNA art and to other areas of biotechnology?

As previously stated, the PTOS believes that the written description guidelines are only applicable to the unpredictable arts, in particular to certain unpredictable areas of biotechnology, rather than to the predictable arts and that the *Lilly* decision specifically confined its holding to "claims of genetic material" at the time of the *Lilly* patent. Moreover, the PTOS believes that since the *Lilly* patent, the state of the art with regards to DNA inventions has advanced and with the advent of technology, such as the Polymerase Chain Reaction, the making of the invention of *Lilly* would be routine to today's skilled artisan. In view of this advancement in the art and with the guideline's heavy reliance on the nature of the invention and the level of predictability in the art, it then follows that written description rejections outside the realm of new matter rejections should remain "rarely applied...to a residuum of cases where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error." *Alpert v. Slatin*, 134 USPQ 296 (CCPA 1962). In other words, the PTOS believes that the guidelines should result in a limited number of rejections being made in this art.

This does not mean that the written description rejection should never be applied to biotechnological inventions. The PTOS recognizes that there are some cases biotechnology that are unpredictable. Accordingly, the guidelines should only be applied

to *highly* unpredictable areas in biotechnology on a case-by-case basis where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error. In such instances where the guidelines are followed and a written description rejection is deemed appropriate, the PTOS believes that the Examiner should follow current M.P.E.P. practice with regards to providing objective evidence supporting the rejection and the unpredictable nature of the art.

Despite this belief, it appears that the guidelines may have broader applicability than originally envisioned as discussed above. Without further guidance and examples, it is unclear as to how to apply these guidelines consistently across the vast art of biotechnology. With that said, the PTOS requests that the PTO either revise the guidelines and include examples as to how the written description rejection should or should not be applied to other biotechnological inventions outside the context of the DNA art and/or provide the appropriate training to the Patent Examining Corps.

(iii) Are the guidelines applicable to process and product-by-process claims?

The PTOS believes that the guidelines are deficient and should address process and product-by-process type claims. The PTOS believes this omission will raise serious questions. The following example exemplifies a situation that the PTOS believes is quite possible. Suppose an applicant submitted claims directed to a recombinant polypeptide produced by the expression of a nucleotide sequence wherein neither the nucleotide nor the amino acid sequence has been disclosed and while other relevant identifying characteristics for the polypeptide have been presented, none have been provided for the nucleotide sequence. Following the guidelines, the disclosure is lacking a written description for the nucleotide sequence. However, the examiner must also ask, "Does this

then apply to the claimed recombinant polypeptide produced by the expression of the nucleotide sequence?" Similarly, in a process claim drawn to producing or using a product such as the polypeptide, if the polypeptide itself lacks written description, how about the process?

While the guidelines state that they are directed primarily to determining whether there is written description support for product claims and are not intended to specifically address the description necessary to support process or product-by-process claims, the PTOS believes that the above example demonstrates that guidance in this matter cannot be ignored.

2) Accuracy of the methodology:

The PTOS believes that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is question of fact. *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Following the analysis and the methodology outlined in the guidelines, uncertainties and thus potential problems exist in sections C(2) and D(2) of the guidelines which could result in the inconsistent application of these guidelines. The uncertainties of sections C(2) and D(2) beget several questions - How many identifying characteristics are required? What characteristics are considered relevant? How many species must be presented? What constitutes a representative number?

For instance, in species situations such as C(2) where the complete structure is not disclosed, the guidelines call for a determination of whether the specification discloses sufficient relevant identifying characteristics. However, it is unclear as to how "relevant" or "sufficient" identifying characteristics are established. While the examples provided in

the guidelines set forth some of these other relevant identifying physical characteristics, e.g., size, molecular weight, cleavage map, origin, activity, and specificity, it is unclear as to what constitutes a "sufficient" number and it remains unclear as to what other "relevant" identifying characteristics can be utilized. In addition, it is unclear as to how functional properties fit into this analysis.

Similarly, potential problems exist in genus situations such as D(2) where a representative number of species have not been described in complete structure. In this situation where a genus is claimed as in D(2) and a representative number of species by complete structure has not been disclosed, the guidelines call for the examiner to determine whether the specification describes by sufficient relevant identifying characteristics a representative number of species, i.e., structure or other physical and/or chemical characteristics, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. The guidelines indicate that a "representative number of species" requires that the species which are expressly described be representative of the entire genus. When there is substantial variation within a genus, it may require a description of the various species which reflect the variation of the genus. The guidelines further indicate that what constitutes a "representative number" is an inverse function of the predictability of the art. For instance, the guidelines indicate that in an unpredictable art, adequate written description of a genus cannot be achieved by disclosing only one species within the genus. Despite this instruction, it remains unclear as to how relevant identifying characteristics are established. In addition, it is unclear as to what constitutes a representative number of

species. Likewise, it is unclear as to what is considered "substantial variation"? Furthermore, it is unclear as to how "a well established correlation between structure and function in the art" is determined. The examples in the guidelines appear to rely heavily on structure and/or physical properties without regard to functional properties. As such it is unclear as to how functional properties fit into the analysis.

Absent further guidance, the PTOS is concerned with the level of uncertainty when it comes to cases where the complete structure is not disclosed or the structure is not disclosed and only a few identifying characteristics are disclosed. Similarly, the PTOS is concerned that determining what constitutes a sufficient number of representative species should be made more clear in the guidelines. Despite these uncertainties, the PTOS believes that the Patent Examining Corps is a highly trained group of individuals who can be relied upon to make this "judgment call", however clear guidance as to the intent the PTO wishes to direct policy on this issue would be appreciated. In addition, the PTOS believes that continued training offered to the biotechnological corps on these guidelines is absolutely essential in establishing sound and fair policy with regards to these guidelines.

3) Impact of these guidelines on pending and future applications.

It is clear that *University of California v. Eli Lilly* and *Fiers v. Revell,* present significant problems to past, present, and future applications. Both of these cases involved claims directed to genetic material or DNA which apparently satisfied current examination practices at the time of examination. However, despite this, the Federal Circuit explicitly criticized the manner in which they were enabled. In *Fiers*, the Federal Circuit stated that

> "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not

> do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for (β-IF). A bare reference to DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA."

Similarly, in *Lilly*, the patent claimed human insulin cDNA and disclosed the full-length amino acid sequence of insulin and the full-length nucleotide sequence of rat insulin cDNA. The Federal Circuit ruled this was insufficient to satisfy the written description requirement and stated that the written description must be satisfied by "a precise definition [of the claimed DNA or protein] such as a structure, formula, chemical name, or physical properties."

Hence, the explicit text of these decisions clearly present problems as to the validity of the past and the current examination practices in that the written description requirement for nucleotide sequences may not be satisfied unless the exact nucleotide sequence - or a detailed description of the class of nucleotide sequence is present in the patent disclosure. This raises serious questions as to how examiners are expected, if at all, to address this situation if the applicant wishes to comply with these cases. For instance, the guidelines do not guide the examiner in how to suggest amendments to bring the claims into compliance. The PTOS is concerned that the examiners will be faced with difficult procedural positions as applicants try to employ appropriate responses to these cases. Furthermore, in future applications, examiners may be ill-equipped to deal with evaluating the sufficiency of applicant's efforts in satisfying this requirement. Therefore, although these guidelines can be used to address future applications, the PTOS specifically requests that written guidance for currently pending applications be prepared as well

Conclusion

In conclusion, the PTOS believes that the written description guidelines have application only in the unpredictable arts, in particular to a limited number of biotechnology cases, rather than in the more predictable arts and that the *Lilly* decision specifically confined its holding to "claims of genetic material" and to the facts at the time of the *Lilly* patent. Despite this belief, it appears that the courts intend for the broad application of the written description requirement to the predictable arts as well. Accordingly, while the "Written Description Guidelines" are appropriate in that they will guide the examiner during the examination process of nucleic acid product claims to a correct assessment of whether the disclosure complies with the written description requirement, they are incomplete with regards to the applicability across the different arts. In addition, with regards to process and product-by-process type claims, the PTOS notes that the guidelines fail to address the written description problems associated with these types of claims. Therefore, the PTOS supports the guidelines as they pertain to nucleic acid product claims, and it notes that the guidelines do not fully remedy the stir caused by the recent court decisions mentioned above with regard to their applicability across a wide range of art, and as they apply to process and product-by-process type claims. Once again, the PTOS would like to express its appreciation for this opportunity to comment.